

COURTNEY M. PRICE
VICE PRESIDENT
CHEMSTAR



December 30, 2003

201-15005

VIA U.S. Mail and Email

Administrator, Michael O. Leavitt
U.S. Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 22116
Attention: Chemical Right-to-Know Program

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**Re: Acetylene Panel; High Production Volume (HPV) Challenge Program;
Submission of Test Plan and Robust Summaries**

Dear Administrator Leavitt:

The American Chemistry Council's Acetylene Panel is pleased to submit its *Test Plan for Acetylene* (CAS No. 74-86-2). This submission consists of the following documents:

1. *Test Plan for Acetylene* – This test plan uses existing available data, modeling, information on the next higher homolog (methylacetylene, CAS No. 74-99-7), and a technical discussion to address the Screening Information Data Set (SIDS) endpoints; and
2. IUCLID Data Set.

The Panel has very recently become aware of additional data that may be relevant to the *Test Plan for Acetylene*. Evaluation of this data is underway and when it is completed, the test plan may be revised accordingly.

The current members of the Acetylene Panel are: Air Liquide America Company; BASF Corporation; Chevron Phillips Chemical Company; Dow; DuPont; Equistar Chemicals, LP; Praxair, Inc.; Rohm and Haas Company; and Shell Chemicals Limited.



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Michael O. Leavitt
Acetylene Panel Test Plan Submission
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This submission is also being sent electronically to the following email addresses:

Oppt.ncic@epa.gov
Chem.rtk@epa.gov

If you have any questions or require additional information, please call the Acetylene Panel's technical contact, John DiLoreto, at (703) 741-5615 or via email at John_DiLoreto@AmericanChemistry.com.

Sincerely yours,

Courtney M. Price
Vice President, CHEMSTAR

Attachments: 1) *Test Plan for Acetylene* (CAS No. 74-86-2)
2) IUCLID Data Set

cc: Acetylene Panel Members

201-15005A

High Production Volume Challenge

Test Plan

for

**Acetylene
CAS No. 74-86-2**

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Prepared by:

**American Chemistry Council
Acetylene Panel**

December 30, 2003

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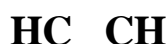
1.0 Introduction

The Acetylene Panel¹ (Panel) of the American Chemistry Council (ACC) has agreed to supply screening level hazard and use information under the U.S. EPA High Production Volume (HPV) Challenge Program for acetylene (CAS No. 74-86-2). This plan identifies existing data of adequate quality for this chemical, and how the data serve to address the HPV Challenge screening endpoints.

2.0 Designation of Test Substance

Test Substance

The test substance presented in this test plan is acetylene (CAS No. 74-86-2). Its molecular structure is as follows:



Acetylene is a well-known industrial gas. It is the lowest molecular weight analog of the class of neutral organic, acetylenic compounds. This substance is also known as ethyne.

Nearest Analog

The next higher homolog (nearest analog) of acetylene is methylacetylene (CAS No. 74-99-7), also known as propyne or 1-propyne. Its molecular structure is as follows:



Data for methylacetylene will be used to address the repeat dose and bacterial reverse mutation assay endpoints for acetylene in this test plan. Information for methylacetylene should be predictive of acetylene for the following reasons:

- Methylacetylene, as the next higher acetylenic homolog, is the most closely related chemical to acetylene in molecular structure and size, and has the identical functionality (the carbon-carbon triple bond);
- Methylacetylene, also a gas at ambient temperatures, exhibits physical/chemical properties that are similar to acetylene, as shown in Table 1; and
- The acute toxicity of methylacetylene in mammals is closely similar to that of acetylene.

The reasons for choosing methylacetylene are consistent with the EPA draft guidance for “The Use of Structure- Activity Relationships (SAR) in the High Production Volume Chemicals Challenge Program.” Based on a review of the data, it is concluded that methylacetylene is a valid analog for acetylene and that the uptake, metabolism, ecotoxicology and health effects of the two compounds is

¹ The current members of the Acetylene Panel are: Air Liquide America Company; BASF Corporation; Chevron Phillips Chemical Company; Dow; DuPont; Equistar Chemicals, LP; Praxair, Inc.; Rohm and Haas Company; and Shell Chemicals Limited.

expected to be very similar. Therefore, data comparison is used for those instances where valid and reliable data are available for methylacetylene but not for acetylene.

Manufacture of Acetylene

In the United States, seven companies currently manufacture acetylene for use primarily as a chemical intermediate that is used in closed systems. U.S. manufacturing capacity in 2001 totaled 333 million pounds (Laeson et al., 2001). This capacity included both captive and merchant capabilities, but did not include smaller amounts made by industrial gas producers for use in acetylene torches.

The major producers in the U.S. manufacture acetylene by either the partial oxidation of natural gas or as a co-product from the steam cracking of ethylene (Kirk-Othmer, 1995). Acetylene produced by either method is used primarily as a closed system industrial intermediate. Minor producers manufacture smaller amounts of acetylene by reacting calcium carbide with water manufactured using the carbide process. This acetylene is used primarily in acetylene torches.

Uses of acetylene

In the year 2000, approximately 80% of U.S. production was used as a closed system industrial intermediate in the synthesis of other chemicals (Laeson et al., 2001). The remaining 20% of production was predominantly used in oxyacetylene torches for welding and metal cutting (Laeson et al., 2001). Currently, 96% of manufacturing capacity of the 7 major manufacturers is slated for use as a closed system industrial intermediate. Most of this use occurs at the manufacturing sites, because of the economic and physical impracticality of transferring large quantities of acetylene gas to other sites. Some acetylene is also transferred through pipes to neighboring facilities for conversion to other products. Products made from acetylene include vinyl chloride monomer, acetylene black, vinyl fluoride, N-vinylcarbazole, N-vinylcaprolactam and other derivatives such as 1,4-butanediol, vinyl ethers, N-vinyl-2-pyrrolidone, and vinyl esters. Acetylene was used in the early 1900's as an anesthetic (under the name Narcylene). It is no longer used as an anesthetic because better, less explosive alternatives are available. No uses of acetylene in consumer products are known. Since the majority of acetylene is used as a closed system industrial intermediate and as a fuel for oxyacetylene torches, minimal occupational exposure, with no consumer exposure, is expected.

3.0 Criteria for Determining Adequacy of Data

All identified available studies were reviewed and assessed for adequacy according to the standards of Klimisch et al. (1997). Studies receiving a Klimisch rating of 1 or 2 are considered to be adequate.

4.0 Available Data

The summary of available data for acetylene (as shown in Table 5) was constructed after a careful evaluation of all identified existing data (see below).

4.1 Chemical and Physical Properties

Key chemical/physical properties of acetylene and methylacetylene are discussed in the following sections and summarized in Table 1.

4.1.1 Melting Point

A melting point of -80.8°C for acetylene is reported by Lide (1992-1993). The same reference cites a melting point of -101.5°C for methylacetylene.

4.1.2 Boiling Point

A boiling point of -84°C is reported for acetylene by Lide (1992-1993). The same reference cites a melting point of -23.2°C for methylacetylene.

4.1.3 Vapor Pressure

A vapor pressure of 6,969.2 hPa is reported for acetylene by Daubert and Danner (1989). This value was calculated from experimentally derived coefficients. The vapor pressure of methylacetylene is 5,155 hPa (Clayton and Clayton, 1981-2).

4.1.4 Octanol/Water Partition Coefficient

The method of Hansch and Leo (1995) was used to estimate a log Kow of 0.37. The same method was used to estimate a log Kow of 0.94 for methylacetylene.

4.1.5 Water Solubility

A measured water solubility of 1,230 mg/l at 1,010 hPa and 20°C is cited in Grayson (1978). This value is consistent with the water solubility value of 1,200 mg/l reported in the Hazardous Substances Data Bank (2003). These values indicate that acetylene theoretically has appreciable water solubility. However, the likelihood that acetylene concentrations in water would ever approach this level (except under controlled or forced conditions) is remote based on its very strong tendency to volatilize to its normal gaseous state (See Table 2 and Section 4.2.3). The water solubility of methylacetylene is reported to be 3,640 mg/l (McAuliffe, 1966).

4.1.6 Explosivity

Acetylene is a gas that forms highly explosive mixtures in air across a broad range of concentrations. The lower explosive limit (LEL) is 2.5% (25,000 ppm) in air (National Fire Protection Association, 1997).

4.1.7 Summary/Test Plan for Physical Properties

Acetylene has been a commercial industrial chemical for many decades, and its key physical properties are well established. Although the data were determined long ago (and therefore not generated using current guideline methods), the data should be accepted as reliable. Measured data are available for many of the required physical property endpoints. The melting and boiling points are -80.8°C and -84°C, respectively. The calculated vapor pressure is 6,969.2 hPa at 25°C. The

estimated octanol/water partition coefficient is 0.37. Based on its very high vapor pressure, both the estimated partition coefficient and the appreciable water solubility of 1,200 mg/l are largely of only theoretical relevance. No new testing for physical properties is proposed.

Table 1 shows the comparison of physical properties for acetylene and the nearest analog, methylacetylene. The similarities of these properties are noted.

Table 1. Chemical/physical Properties of Acetylene and Methylacetylene

<i>Endpoint</i>	<i>Acetylene</i>	<i>Methylacetylene</i>
Molecular weight (grams/mol)	26.04	40.07
Melting point	-80.8°C ^a	-101.5°C ^a
Boiling point (at 1016 hPa)	-84 °C ^a	-23.2°C ^a
Relative density (at -82°C)	0.6208 ^a	0.7062 ^a
Vapor pressure (hPa)	6,969.2 ^b (at 25° C)	5,155 ^a (at 20° C)
Partition coefficient (Log Pow or Kow)	0.37 ^b	0.94 ^b
Water solubility (mg/l at 25 ° C)	1,230 ^a	3,640 ^a

^a Measured value; ^b Estimated value

4.2 Environmental Fate/Pathways

The results of environmental fate modeling and studies are discussed below and summarized in Table 2.

4.2.1 Photodegradation

Photodegradation with hydroxyl radical sensitizer was estimated using EPIWIN/Aop (v1.90). An overall hydroxyl radical rate constant of 8.15 E-13 cm³/(molecule*sec) was calculated based on the summation of individual rate constants for each bond fragment in the molecule using the program algorithm. A half-life of 13.1 days was calculated assuming a constant concentration of OH radical and pseudo first order kinetics. Since acetylene is a gas (except at temperatures well below 0°C), atmospheric photodegradation is expected to be the most significant route of degradation in the environment.

4.2.2 Stability in Water

Because the material is a gas, rapid volatilization is by far the relevant environmental fate pathway for acetylene in the hydrosphere. Therefore, it is not necessary to conduct experiments to determine water stability. Since acetylene does not contain functional groups that are known to be readily hydrolyzed (i.e., ester groups, nitriles, amides, etc.), it is not expected to hydrolyze readily under neutral ambient conditions. The carbon-carbon triple bond is generally recognized to be stable in water. Therefore, the small amount of material that may be present in the hydrosphere is expected to remain intact until it evaporates.

4.2.3 Fugacity

Level III fugacity modeling has been conducted on acetylene using the EPIWIN model. Inputs to the program were CAS No. 74-86-2, a melting point of -80.8 °C, a boiling point of -84°C, a vapor pressure of 6,969.2 hPa and water solubility of 1,200 mg/l. The emission rate inputted into the program for air was 1,000 kg/hr (model default value). The emission rates inputted to water, soil and sediment were 0 kg/hour. These emission rates are more in keeping with manufacturing and use processes that are extremely unlikely to emit significant emissions to these media, and forcing acetylene into these media would be very difficult based on the physical properties of acetylene. Model default emissions of 1,000 kg/hr (87,600,000 kg/year) to the air are beyond reasonable worst-case assumptions, especially from point sources. The following half-lives were calculated: $T_{1/2\text{air}} = 298$ hrs, water = 360 hrs, soil = 360 hrs, and sediment = 1,440 hrs. A Henry's Law Constant of 0.024 atm-m³/mol and a soil sediment partition constant (K_{oc}) of 14.3 were estimated using the EPIWIN/Henry and PCKOC Programs, respectively. The percent mass balances predicted for acetylene in air, water, soil and sediment are shown in Table 3. The results show that 99.9% of acetylene will remain in the atmosphere after being discharged into it.

4.2.4 Biodegradation

Since acetylene is a gas and 99.9% partitions to the air according to the Fugacity Level III model, biodegradation is not an important route for removal of the material from the environment. Furthermore, since standard OECD biodegradation tests are not designed to assess the relative biodegradability of gaseous materials, such tests will be difficult to perform and will not adequately assess the ability of the material to biodegrade in the environment. Since the material is a gas, the primary means of degradation of the vast majority of the material in the environment is photodegradation, which supports the conclusion that biodegradation is irrelevant.

4.2.5 Summary/Test Plan for Environmental Fate Parameters

Estimated values are available for the hydroxyl radical induced photolysis rate constant and atmospheric half-life, Henry's Law Constant and Fugacity Level III environmental transport parameters. These values indicate that acetylene has a very strong tendency to partition to the atmosphere, where it undergoes photodegradation. Standard biodegradation tests have not been performed with acetylene and are not considered relevant studies to conduct on a gas that will mainly partition to air. Although the material is expected to be stable in water, any material present in water will rapidly evaporate. Therefore, no testing for water stability (hydrolysis) is proposed.

Table 2. Environmental Fate Parameters for Acetylene

<i>Endpoint</i>	<i>Value</i>
Indirect Photolysis (OH sensitizer) (Hydroxyl Radical Rate Constant) ^a (Atmospheric $T_{1/2}$) ^a	8.15 E-13 cm ³ /molecule-sec 13.1 days
Stability in Water	Should not hydrolyze
Henry's Law Constant ^a	0.024 atm-m ³ /mol
Environmental transport (Fugacity Level III mass percentages) ^a	Air = 99.9 Water = 0.104 Soil = 0.0101 Sediment = 0.000177
Biodegradation	Not applicable

^a Estimated using EPIWIN

4.3 Aquatic Ecotoxicity

Since acetylene is a gas that will partition to air and rapidly evaporate from the aqueous environment, ecotoxicity testing is not considered relevant. Nonetheless, some toxicity tests have been conducted in several aquatic species. The results of this testing (along with ECOSAR modeling) are discussed below and summarized in Table 3.

Table 3. Ecotoxicity of Acetylene

<i>Species</i>	<i>LC50/EC50 (mg/l) (time)</i>
Fish (unspecified)	approx. 500 ^a (96 hour)
Lepomis sp.	> 1,000 (1 hour) ^b
Minnow (unspecified)	> 17 (1 hour) ^b
Trout fingerlings	200 (33 hour) (limit of toxicity) ^b
Cyprinus auratus (goldfish)	400 (24-48 hour) (limit of toxicity) ^b
Fingerling chinook salmon	3,500 (72 hours) (limit of toxicity)
Young rainbow trout	3,000 – 5,000 (72 hours) (limit of toxicity)
Daphnia magna	approx. 480 ^a (48 hour)
Green algae	approx. 275 ^a (96 hour)

^a Estimated using EPIWIN; ^b Given a reliability rating of 4 due to lack of information

Since experimental conditions were not listed and the primary references were not available for the fish toxicity studies, it is not known whether the concentrations listed are nominal or measured, or if the studies were conducted using flow through or static methods. If the experiments were performed using closed systems that would force acetylene into the water and minimize volatilization, the relevance of the results for the aquatic environment would be questionable. Such attempts would eliminate airspace around the liquid and lead to deoxygenation. In conclusion, the testing and modeling that have been done are adequate for HPV purposes. No additional testing is proposed.

4.3.1 Acute Toxicity to Fish

The 96-hr LC50 value for fish estimated by EPA's ECOSAR model for the neutral organic class is approximately 500 mg/l. This is similar to concentrations reported as causing death to an unknown number of trout fingerlings and goldfish in the OHM/TADS database, and less than concentrations reported to cause toxicity in fingerling chinook salmon and young rainbow trout. The concentrations reported for salmon and rainbow trout (3,500 and 3,000-5,000 mg/l respectively) are suspect, since, these values exceed the measured water solubility of acetylene. Since references for these studies were not given in the database and were not available, they could not be reviewed. Therefore, reliability ratings of 4 (not assignable) were designated for these studies.

4.3.2 Acute Toxicity to Aquatic Invertebrates

EPA's ECOSAR model for the neutral organic class predicts a 48-hour EC50 value of approximately 480 mg/l for *Daphnia*. No experimental test data were available.

4.3.3 Acute Toxicity to Aquatic Plants

The 96-hr EC50 value calculated for green algae by the ECOSAR model for the neutral organic class is approximately 275 mg/l. No experimental test data were available.

4.3.4 Summary/Test Plan for Ecotoxicity

The available ecotoxicity data, combined with the ECOSAR results, adequately address the ecotoxicity endpoints for HPV purposes. Since the material is a gas, it will evaporate quickly from water. Tests that are performed in closed systems in the laboratory will not adequately simulate environmental conditions in which acetylene will remain in the atmosphere. Experimental studies performed to prevent volatilization may also be accompanied by deoxygenation, which is not expected to actually occur in environmental bodies of water. In the aqueous environment, acetylene should not be present at concentrations estimated by ECOSAR to cause toxicity to aquatic species. No additional ecotoxicity testing is proposed.

4.4 Human Health Data

Because acetylene is a gas, it is not relevant to test the material using oral or dermal routes of application. Inhalation is the only significant potential route of exposure.

4.4.1 Acute Mammalian Toxicity

With decades of production and use, the acute toxicity of acetylene is well understood to be that of a simple asphyxiant. Data regarding the acute inhalation toxicity to animals and humans clearly show that acetylene is of a very low acute toxicity. Overall, the data support a rat LC50 > 100,000 ppm.

In humans, acetylene is not acutely toxic below its lower explosive limit of 2.5% (25,000 ppm). Inhalation of 10% acetylene (100,000 ppm) for 1 hour does not cause acute toxicity. Inhalation of 33% or 35% has caused unconsciousness within 7 and 5 minutes, respectively (Davidson, 1925). Two deaths and a near fatality occurred after inhalation of 40% acetylene during manufacture with calcium carbide (Carreñ, 2000; Jones, 1960). The cause of these deaths was attributed to the phosphate and arsine impurities in crude acetylene and carbon monoxide present in the work area.

In rats, a concentration of 78% acetylene (780,000 ppm) produced anesthesia in 15 minutes, and inhalation of 90% for 2 hours caused respiratory failure (Riggs, 1925). Inhalation of 850,000 ppm caused increased respiratory volume and frequency and induced anesthesia in dogs, with rapid recovery (Heymans and Bouckaert, 1925). Therefore, the LC50 value in this study was greater than 850,000 ppm.

4.4.2 Repeated Dose Mammalian Toxicity

In 1933, Franken and Miklos looked for possible organ damage from the administration of acetylene at anesthetic concentrations to rats, mice, guinea pigs, rabbits, and dogs. Animals were exposed to acetylene in oxygen according to the scheme presented in Table 4.

Table 4. Test Conditions and Results for Franklin and Miklos Study (1933)

<i>Animal</i>	<i>Number Tested</i>	<i>Conc. (%)</i>	<i>Daily Exposure Time (hours)</i>	<i>Number Of Days Exposed</i>	<i>Total Exposure Time (hours)</i>	<i>Deaths</i>
Rat	16	25	1	7-93	7-93	6
Rat	10	50	2	1-8	2-16	9
Guinea Pig	7	50	2	1-9	2-18	7
Mouse	5	50	2	1-6	2-12	5
Rat	47	80	½	2-36	1-18	36
Rat	8	80	1	14	14	0
Guinea Pig	6	80	1	10	10	0
Rabbit	4	80	1	6-10	6-10	3
Dog	2	80	1	12	12	1

At the lower concentrations (concentrations were not stated) the animals appeared only slightly sleepy. At higher concentrations the majority of animals fell asleep after 15-20 minutes. In general, these animals were not in deep narcosis. The rats, rabbits, guinea pigs and dogs generally recovered from narcosis in a short time. However, the mice did not survive treatment. Some of the animals died spontaneously. Pneumonia was observed in most of these cases. Since pneumonia also was observed in control animals exposed only to air, it does not appear to be related to treatment. In treated animals that survived to termination, the authors found no evidence of cellular injury to the parenchymatous cells of the heart, lungs, liver, kidneys, or spleen. However, capillary hyperemia of the liver, kidneys and spleen was observed in some rats exposed to 25%. This effect was observed until at least the second day after the last exposure to the gas but was not evident in animals killed later (up to 5 days after the last exposure). Since capillary hyperemia was not observed in rats exposed to higher concentrations of acetylene, it does not appear to be test-material related. In conclusion, since repeated exposure of rats to a concentration (25%) that greatly exceeds any concentration that would be expected to occur in routine human working conditions did not cause any organ toxicity, it is expected that repeated exposure of humans to concentrations routinely encountered in the workplace would not cause organ toxicity.

The repeated dose toxicity of the analog methylacetylene has been studied in rats and dogs (Horn et al., 1957). In this study, the animals were exposed to 28,700 ppm methylacetylene 6 hr/day, 5 days/week for 6 months. Rats and dogs reached an early plane of anesthesia (within 30 minutes) and generally recovered rapidly after each exposure. Forty percent of the rats and none of the dogs died over the course of the study. Gross pathology of the rats that died was limited to the lungs, which appeared dark red and remained distended when the thorax was opened. In exposed rats that survived to termination, the lungs also were discolored and remained distended. Microscopic pathology of the lungs showed definite pulmonary irritation. The remaining organs appeared to be within normal limits. There was no effect of treatment on any hematological, urine or biochemical index of toxicity in the dogs. The gross appearance of all organs examined and microscopic examinations of the lung, liver, kidney, heart, spleen and GI tract in exposed dogs were normal. Overall, the authors of the study concluded that methylacetylene is of low repeated dose toxicity and the site of toxicity was limited to the lungs, even at extremely high concentrations (28,700 ppm).

4.4.3 Genetic Toxicity

4.4.3.1 Mutagenicity

In an Ames test employing three strains of *S. typhimurium* (TA97, TA98, TA100), acetylene did not induce mutations in both the absence and presence of metabolic activation (Hughes et al., 1984). This test was given a reliability rating of 2 (valid with restrictions), since current guidelines recommend testing in 4 different *S. typhimurium* strains and a strain of *E. coli*.

In a more recent test conducted in *S. typhimurium* TA98, TA100, TA1535 and TA1537 and *E. coli* WP2uvrA, the related material methylacetylene did not cause an increase in mutations in any strain of Salmonella at any concentration in the absence or presence of metabolic activation (Araki et al., 1994). However, there was a dose dependent increase in the number of mutations in *E. coli* WP2 uvrA in the absence or presence of metabolic activation.

Overall, the weight-of-evidence on acetylene and its surrogate (methylacetylene) indicate that acetylene is not mutagenic.

4.4.3.2 Chromosomal Aberration

No chromosome aberration tests were identified for acetylene or methylacetylene. Available information suggests, however, that exposure to acetylene would not result in chromosomal damage. This endpoint is considered fulfilled for HPV purposes and it is deemed not appropriate or relevant to conduct new testing for the following reasons, discussed in further detail in Section 4.4.4:

- The American Conference of Governmental Industrial Hygienists (ACIGH) Threshold Limit Value (TLV) Committee did not consider acetylene to be of reproductive concern when establishing a TLV, which is based on acetylene being a simple asphyxiant;
- As acetylene is used primarily as a closed system industrial intermediate, or as a welding gas where it is combusted, there is only a remote likelihood that human beings can be exposed to meaningful concentrations of acetylene, even in the workplace;
- Acetylene has been used for over 100 years as an anesthetic and industrial chemical and during this time period no link between genetic toxicity and the use of acetylene has been established; and
- A high fire and explosion hazard would be associated with any testing at meaningful concentrations.

4.4.4 Reproductive and Developmental Toxicity

No adequate reproductive or developmental toxicity studies have been located for acetylene. It is not deemed appropriate or relevant to conduct new testing for these endpoints for these reasons (which are discussed in greater detail below):

- The American Conference of Governmental Industrial Hygienists (ACIGH) Threshold Limit Value (TLV) Committee did not consider acetylene to be of reproductive concern when establishing a TLV, which is based on acetylene being a simple asphyxiant;

- As acetylene is used primarily as a closed system industrial intermediate, or as a welding gas where it is combusted, there is only a remote likelihood that human beings can be exposed to meaningful concentrations of acetylene, even in the workplace;
- It has been demonstrated that acetylene is minimally toxic to mammals, except at exceedingly high doses. The repeated dose study on the acetylene surrogate methylacetylene indicated effects only at the site of administration (lungs), and no effects at other organs. Evidence indicates that mammals do not metabolize acetylene but instead eliminate acetylene rapidly and unchanged from the lungs. Reproductive and developmental effects are not likely to occur as they would be effects that are remote to the lungs;
- Acetylene has been used for over 100 years as an anesthetic and industrial chemical and during this time period no link between any reproductive or developmental effect and the use of acetylene has been established; and
- A high fire and explosion hazard would be associated with any testing at meaningful concentrations.

These reasons are discussed in further detail below.

4.4.5 Other Health Information

ACGIH Classifies Acetylene as a Simple Asphyxiant

The ACGIH has reviewed the toxicology of acetylene and found no reason to assign a TLV for the workplace, giving acetylene a simple designation as an asphyxiant (ACGIH, 2003).

Inability to Expose Workers or General Population to Meaningful Concentrations of Acetylene

Approximately 80% of acetylene produced is used as a closed system industrial intermediate to manufacture other chemicals. Much of this use is at the same site as manufacture, with the acetylene being transferred from the closed manufacturing and storage units to the conversion units via pipes. The other primary use (approximately 20% of production) is in oxyacetylene torches for welding and metal cutting where mixtures of acetylene/air or acetylene/oxygen mixtures are burned to provide a very high temperature heat source. In this operation, acetylene gas is released from closed cylinders through a nozzle jet that is ignited to form the hot flame. In welding, acetylene undergoes essentially complete combustion in the process. Acetylene is contained in enclosed equipment during manufacture, storage, transport and use. Acetylene is not believed to be present in consumer products. While it is possible that acetylene gas could escape from gas cylinders, enclosed reactors, pipes and storage tanks, such escape would be a result of a non-routine, emergency circumstance, such as a line rupture or failed valve. In such cases, immediate action is required to prevent escape of significant quantities, since just 2.5% or greater concentrations in air form explosive and combustible mixtures that are given the highest flammability hazard ratings. Therefore, air concentrations must be held to much lower levels, and work areas must be evacuated if significant air concentrations start to develop via accidental release. In summary, the most meaningful hazard associated with acetylene is fire and explosion that would be life-threatening before toxicological hazards could develop.

Simple diffusion model calculations show maximum expected 1-hour average ambient concentrations at approximately 5.5 ppm, and at approximately 3 ppm for 24-hour values of acetylene near a plant boundary. Urban concentrations of approximately 80 ppb and rural values of 1 ppb have been measured. Based on the “low toxicity and expected low ambient concentrations, acetylene does not pose a health or environmental hazard as an air pollutant” (Patterson et al., 1976).

Demonstrated Minimal Toxicity

Acetylene is not acutely toxic below its lower explosive limit of 2.5% (25,000 ppm). It has been well established that acetylene behaves in mammalian systems primarily as a central nervous depressant and asphyxiant at high dose levels (100,000 ppm in air or above). It produces varying degrees of temporary and reversible narcosis when administered with oxygen in concentrations of $\geq 100,000$ ppm (10% in air). Repeated exposure of rats, mice, guinea pigs rabbits and dogs to concentrations $\leq 800,000$ ppm showed no evidence of cellular injury to the parenchymatous cells of the heart, lungs, liver, kidneys, or spleen (Franklin and Miklos, 1933). The only histologic findings in rats exposed an anesthetic concentration (28,700 ppm) of the related material methylacetylene for 90 days were confined to the lungs (Horn et al., 1957).

Limited data reported in the literature indicate that acetylene is rapidly absorbed and eliminated unchanged in the body (Adriani, 1952, 1962). The blood-gas partition coefficient of acetylene at normal hematocrit and body temperature is 0.833 (Jibelian et al., 1981), indicating that the material has a greater propensity to be removed from blood than to be retained in it. Schrikker et al. (1989) have shown that, in man at rest, the rates of alveolar and mixed venous washout for acetylene calculated from the slopes of the of the alveolar plateau are 2.6% and 4.8% per second, respectively. Within 10 minutes of inhalation of acetylene for 15 minutes, the end tidal concentration was 8.0 % of its initial value. Together, these data support the contention that the lungs rapidly excrete acetylene. The gas also diffuses rapidly from the peritoneal and pleural cavities and diffuses through the skin. Therefore, acetylene is unlikely to persist in the body, even after repeated exposure to low concentrations that may be encountered in the workplace.

Long History of Use

Acetylene has been used for over 100 years as an anesthetic and industrial chemical, and few complications of using this gas have surfaced. According to the Hazardtext database, “there is no scientific evidence that repeated exposure to tolerable levels of acetylene leads to deleterious health effects.” Epidemiological studies that have been published have failed to establish a link between use of acetylene and cancer. Exposure to acetylene is not associated with liver angiosarcoma in workers exposed to a number of materials (Waxweiler, 1981). Acetylene exposure also was not a risk factor in mortality from lung cancer in a case-referent study in which exposure to chemicals in an acetylene and phthalic anhydride plant accounted for one third of the total number of lung cancer deaths (Riboli et al., 1988). In a pilot study conducted on 454 men, no associations were found between occupational exposure to acetylene and development of cancer (Siemiatycki et al., 1982). In a study conducted on 370 workers involved in acetylene cylinder manufacture between 1935 - 1975, an excess of deaths from lung cancer, and cancer of the stomach and pancreas was observed. However, an association between exposure to acetylene and lung cancer was not identified (Newhouse et al., 1988). Acetylene also was not listed as a risk factor for developing cancer in a study involving 632 Danish male molders (Hansen, 1991). In two case-controlled studies, acetylene exposure was not identified as a risk factor for developing multiple myeloma (Morris et al., 1986; Williams et al., 1989). In a Texas plant, which utilizes acetylene and other chemicals to produce

acrylate and methacrylate ester, the excess of total cancer deaths in those hired from 1958 to 1962 could not be correlated with job-related causes (Rohm and Haas, 1980).

In an epidemiological study conducted in Russia, the health status of an unknown number of pregnant women chemists who produced acetylene-vinyl acetate from 1972-1975 was compared to that of 84 pregnant women that did not work with chemicals (Talakina et al., 1977). Twenty percent of the chemists were “sick”, compared to 8% of the controls ($p < 0.001$). The nature of the illnesses was not mentioned; however, they were listed as being associated with temporary disability to work related to pathology of the pregnancy. No chemicals were identified in the study other than acetylene-vinyl acetate. Other materials that the female workers may have been exposed to were not mentioned or quantified. Additional variables that could have affected the results (e.g., age, number of years on the job, smoking, nutritional or social status) were not examined. Since the workers presumably were also exposed to vinyl acetate as well as acetylene, no causative relationship between exposure to acetylene and reproductive toxicity can be identified from this study. Due to the aforementioned limitations, this study cannot be considered valid. No other studies linking exposure of acetylene to any kind of reproductive concerns have been published over a long history of use.

Further Testing Would Be Hazardous

If further studies on acetylene were undertaken, they would provide little additional useful knowledge of the hazards of this substance without leading to study conditions (very high air concentrations) that would present a serious explosion hazard to animals and people. Reproductive and developmental testing would require inhalation chambers that contained greater than the lower explosive limit concentration (25,000 ppm) of acetylene in order to demonstrate a toxicological effect. These concentrations would have to be maintained for several hours per day (and confirmed by analytical monitoring) for a number of days. Even if these conditions were achievable without incident, the data presented above indicate that the only manifestation of toxicity that would be observed is narcosis, asphyxiation of test animals, and pulmonary irritation.

4.4.6 Summary/Test Plan for Mammalian Toxicity

Acute and repeated dose studies that have been performed with acetylene in humans and animals and the repeated dose study with a related material (methylacetylene) adequately fill the acute and repeated dose endpoints. The bacterial mutagenicity tests that have been performed with acetylene and methylacetylene adequately characterize the potential for acetylene to cause mutagenicity. Therefore, no new testing of these three endpoints is planned. It is not considered necessary to perform chromosomal aberration or reproductive/developmental toxicity tests in animals to characterize these endpoints since mutagenicity studies indicate a lack of mutations, such toxicity has not surfaced after over a century of use of the material, acetylene is minimally toxic to mammals (except at exceedingly high doses or concentrations which are not likely to be present in the workplace), acetylene is rapidly excreted from the lungs without metabolism, performance of such studies would be extremely hazardous. Since the predominant use is as a closed system intermediate with little potential for exposure and the other use is as a fuel for oxyacetylene welding where the acetylene is consumed, potential exposure is severely limited.

5.0 Summary

Table 5 at the end of this section provides a summary of the available data for acetylene.

Physical Properties

Measured data are available for all required physical property endpoints except vapor pressure and partition coefficient. Acetylene has been a commercial industrial chemical for many decades and was well studied long ago with respect to its physical properties. Although the measured data were not determined by current guideline methods and testing predicated good laboratory practices, the data should be accepted as reliable. The EPIWIN Kowwin-generated value for partition coefficient and the calculated value for vapor pressure is also considered reliable and accurate. No new testing is proposed.

Environmental Fate Properties

Estimated values are available for the hydroxyl radical induced photolysis rate constant and atmospheric half-life, Henry's Law Constant, soil sediment partition coefficient, and Fugacity Level III environmental transport parameters. These values indicate that acetylene has a very strong tendency to partition to the atmosphere, where it undergoes photodegradation. The small amounts of material present in the hydrosphere can be oxidized and reduced by sediment bacteria and are estimated by EPIWIN Biowin to be readily biodegradable. Although a measured hydrolysis rate constant is not available for acetylene, the material is soluble and theoretically stable in water, and any material present in water will rapidly evaporate. Therefore, water stability testing is not proposed.

Aquatic Toxicity

Since the material is a gas, it is not expected to be present in environmental waters at any of the concentrations shown to be toxic to fish or estimated by EPIWIN to be toxic to aquatic species. The utility of tests that have been performed is questionable since experimental details were not available. The hazard in conducting additional tests is not worth the risk, especially since guideline tests will not adequately simulate environmental conditions in which acetylene will remain in the atmosphere. No additional testing is proposed.

Mammalian Toxicity

Acute and repeated dose studies and bacterial mutagenicity tests that have been performed with acetylene and the related material methylacetylene adequately fill these endpoints. Therefore, no new testing of these three endpoints is proposed. No chromosome aberration or reproductive or developmental toxicity testing is proposed, due to the history, nature and uses of the material.

Table 5. Summary of Data Availability for Acetylene (CAS No. 74-86-2)

<i>Endpoint</i>	<i>Availability of Data</i>	<i>Proposed Testing</i>
PHYS/CHEM PROPERTIES		
Melting Point	A	None
Boiling Point	A	None
Vapor Pressure	A	None
Partition Coefficient	A	None
Water Solubility	A	None
ENVIRONMENTAL FATE		
Photodegradation	A	None
Stability in Water	NA	None
Biodegradation	NA	None
Transport between Environmental Compartments (Fugacity)	A	None
ECOTOXICITY		
Acute Toxicity to Fish	A	None
Acute Toxicity to Aquatic Invertebrates	A	None
Acute Toxicity to Aquatic Plants	A	None
HUMAN HEALTH		
Acute Toxicity	A	None
Repeated Dose Toxicity	R	None
Genetic Toxicity-Mutagenicity	R	None
Genetic Toxicity-Chromosomal Aberration	A	None
Reproductive Toxicity	A	None
Developmental Toxicity	A	None

A = Adequate data exists.

R = Read across.

NA = Information is presented which highlights the lack of relevance of data for the endpoint and is therefore, not applicable.

6.0 References

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201-15005B

I U C L I D

Data Set

RECEIVED
09 JAN -6 PM 3:00

Existing Chemical : ID: 74-86-2
CAS No. : 74-86-2
EINECS Name : acetylene
EC No. : 200-816-9
TSCA Name : Ethyne
Molecular Formula : C₂H₂

Producer related part
Company : American Chemistry Council, Acetylene Panel
Creation date : 15.08.2003

Substance related part
Company : American Chemistry Council, Acetylene Panel
Creation date : 15.08.2003

Status :
Memo :

Printing date : 09.12.2003
Revision date : 09.12.2003
Date of last update : 09.12.2003

Number of pages : 31

Chapter (profile) : Chapter: 1, 2, 3, 4, 5, 6, 7, 8, 10
Reliability (profile) : Reliability: without reliability, 1, 2, 3, 4
Flags (profile) : Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE),
Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

1. General Information

Id 74-86-2
Date 21.10.2003

1.0.1 APPLICANT AND COMPANY INFORMATION

1.0.2 LOCATION OF PRODUCTION SITE, IMPORTER OR FORMULATOR

1.0.3 IDENTITY OF RECIPIENTS

1.0.4 DETAILS ON CATEGORY/TEMPLATE

1.1.0 SUBSTANCE IDENTIFICATION

IUPAC Name : ethyne
Smiles Code : C#C
Molecular formula : C2H2
Molecular weight : 26.04
Petrol class :

Reliability : (1) valid without restriction
15.08.2003

1.1.1 GENERAL SUBSTANCE INFORMATION

Purity type : typical for marketed substance
Substance type : organic
Physical status : gaseous
Purity : >=
Colour : colorless, clear
Odour : faint ether or garlic like odor

15.08.2003

(20)

1.1.2 SPECTRA

1.2 SYNONYMS AND TRADE NAMES

1.3 IMPURITIES

1.4 ADDITIVES

1.5 TOTAL QUANTITY

1.6.1 LABELLING

1. General Information

Id 74-86-2
Date 21.10.2003

1.6.2 CLASSIFICATION

1.6.3 PACKAGING

1.7 USE PATTERN

Type of use : industrial
Category : Basic industry: basic chemicals

15.08.2003

1.7.1 DETAILED USE PATTERN

Remark : Used as a chemical intermediate in the manufacture of other chemicals
and in welding.

15.08.2003

1.7.2 METHODS OF MANUFACTURE

1.8 REGULATORY MEASURES

1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES

1.8.2 ACCEPTABLE RESIDUES LEVELS

1.8.3 WATER POLLUTION

1.8.4 MAJOR ACCIDENT HAZARDS

1.8.5 AIR POLLUTION

1.8.6 LISTINGS E.G. CHEMICAL INVENTORIES

1.9.1 DEGRADATION/TRANSFORMATION PRODUCTS

1.9.2 COMPONENTS

1.10 SOURCE OF EXPOSURE

1. General Information

Id 74-86-2
Date 21.10.2003

1.11 ADDITIONAL REMARKS

1.12 LAST LITERATURE SEARCH

1.13 REVIEWS

2.1 MELTING POINT

Value : = -80.8 °C
Sublimation :
Method : other
Year :
GLP : no
Test substance : as prescribed by 1.1 - 1.4

Reliability : (2) valid with restrictions
Peer reviewed data that came from a reliable reference textbook.

Flag : Critical study for SIDS endpoint
15.08.2003 (17)

2.2 BOILING POINT

Value : = -84 °C at 1016 hPa
Decomposition :
Method : other
Year :
GLP : no
Test substance : as prescribed by 1.1 - 1.4

Remark : Sublimes at boiling point. Verschueren, K. Handbook of Environmental Data of Organic Chemicals. 2nd ed. New York, NY: Van Nostrand Reinhold Co., 1983. 154.

Reliability : (2) valid with restrictions
Peer reviewed data that came from a reliable reference textbook.

Flag : Critical study for SIDS endpoint
15.08.2003 (17)

2.3 DENSITY

Type : relative density
Value : = .6208 at -82 °C
Method : other
Year :
GLP : no
Test substance : as prescribed by 1.1 - 1.4

Reliability : (2) valid with restrictions
Peer reviewed data that came from a reliable reference textbook.

15.08.2003 (17)

2.3.1 GRANULOMETRY

2.4 VAPOR PRESSURE

Value : = 6969.2 hPa at 25 °C
Decomposition :
Method : other (calculated)
Year :
GLP : no

2. Physico-Chemical Data

Id 74-86-2

Date 21.10.2003

Test substance : as prescribed by 1.1 - 1.4

Remark : Vapor pressure from experimentally derived coefficients.

Result : Vapor pressure = 40 ATM @ 16.8 DEG C.
Sax, N.I. Dangerous Properties of Industrial Materials. 6th Ed. New York, NY: Van Nostrand Reinhold, 1984. 107.

Reliability : (2) valid with restrictions
Peer reviewed data that came from a reliable reference textbook.

Flag : Critical study for SIDS endpoint

15.08.2003 (3)

2.5 PARTITION COEFFICIENT

Partition coefficient : octanol-water

Log pow : = 0.37 at 20 °C

pH value : = 7

Method : other (calculated)

Year :

GLP : no

Test substance : as prescribed by 1.1 - 1.4

Reliability : (2) valid with restrictions
Data calculated by a reliable source using a recognized document estimation method.

Flag : Critical study for SIDS endpoint

15.08.2003 (13)

2.6.1 SOLUBILITY IN DIFFERENT MEDIA

Solubility in : Water

Value : = 1230 mg/l at 20 °C and 1013 hPa

pH value : = 7

Reliability : (2) valid with restrictions
Data came from a reliable reference textbook.

Flag : Critical study for SIDS endpoint

25.11.2003 (12)

Solubility in : Water

Value : = 1200 mg/l at 25 °C

pH value : = 7

Reliability : (2) valid with restrictions
Data are from a secondary source. The primary source is a reliable reference textbook that was not consulted.

15.08.2003 (21)

2.6.2 SURFACE TENSION

2.7 FLASH POINT

2.8 AUTO FLAMMABILITY

2. Physico-Chemical Data

Id 74-86-2
Date 21.10.2003

2.9 FLAMMABILITY

Result : extremely flammable
Method : other
Year :
GLP : no
Test substance : as prescribed by 1.1 - 1.4

Result : Flammable Limits: Upper: 100% by vol.; Lower 2.5% by vol.
Reliability : (2) valid with restrictions

15.08.2003

(10)

2.10 EXPLOSIVE PROPERTIES

2.11 OXIDIZING PROPERTIES

2.12 DISSOCIATION CONSTANT

2.13 VISCOSITY

2.14 ADDITIONAL REMARKS

3. Environmental Fate and Pathways

Id 74-86-2
Date 21.10.2003

3.1.1 PHOTODEGRADATION

Type : air
Light source : Sun light
Light spectrum : nm
Relative intensity : based on intensity of sunlight

INDIRECT PHOTOLYSIS

Sensitizer : OH
Conc. of sensitizer :
Rate constant : = .000000000000815 cm³/(molecule*sec)
Degradation : = 50 % after 13.1 day(s)
Deg. product :
Method : other (calculated)
Year : 2003
GLP : no
Test substance : as prescribed by 1.1 - 1.4

Remark : Measured inputs to the program were melting point (-80.8 degrees C), boiling point (-84 degrees C), vapor pressure (5240 mm Hg) and water solubility (1,200 mg/l).

Reliability : (2) valid with restrictions
Data were estimated using a model.

Flag : Critical study for SIDS endpoint

15.08.2003

(2)(5)

3.1.2 STABILITY IN WATER

Deg. product :
Method : other (calculated)
Year : 2003
GLP : No
Test substance : as prescribed by 1.1 - 1.4

Remark : Measured inputs to the program were melting point (-80.8 degrees C), boiling point (-84 degrees C), vapor pressure (5240 mm Hg) and water solubility (1,200 mg/l).

Result : EPIWIN Hydrowin cannot calculate hydrolysis rate constant for molecular structures of the acetylene type. Hydrolysis of acetylene in water is likely to be an unimportant pathway, because acetylene does not possess a functional group known to be susceptible to hydrolysis at neutral ambient conditions. Also, despite acetylene's measurable solubility in water, acetylene has a pronounced tendency to quickly volatilize from water to the atmosphere, based on its high vapor pressure and existence as a gas at ambient temperature.

Reliability : (3) invalid

15.08.2003

(9)

3.1.3 STABILITY IN SOIL

3.2.1 MONITORING DATA

3.2.2 FIELD STUDIES

3. Environmental Fate and Pathways

Id 74-86-2
Date 21.10.2003

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Type	: fugacity model level III
Media	: soil - air
Air	: 99.9 %
Water	: 0.104 %
Biota	: 0.000177 %
Soil	: 0.0101 %
Method	: Other
Year	: 2003
Remark	: Measured inputs to the program were melting point (-80.8 degrees C), boiling point (-84 degrees C), vapor pressure (5240 mm Hg) and water solubility (1,200 mg/l). The emission rate values of 1000 kg/hr to air, and 0 kg/hr to water, sediment and soil were inputted.
Result	: Estimated half-lives in various media are: air = 298 hours, water = 360 hours, soil = 360 hours and sediment = 1440 hours. The soil/sediment constant Koc = 14.3, as estimated by the EPIWIN Pckoc Program (v1.66). The Henry's Law Constant calculated by EPIWIN Henry (v3.10) = 2.40 E-002 atm-m ³ /mole.
Reliability	: (2) valid with restrictions Data were calculated using a well-recognized computer estimation program.
Flag	: Critical study for SIDS endpoint
15.08.2003	

(8)

3.3.2 DISTRIBUTION

3.4 MODE OF DEGRADATION IN ACTUAL USE

3.5 BIODEGRADATION

Deg. product	:
Method	: other (calculated)
Year	: 2003
GLP	: No
Test substance	: as prescribed by 1.1 - 1.4
Remark	: Measured inputs to the program were melting point (-80.8 degrees C), boiling point (-84 degrees C), vapor pressure (5240 mm Hg) and water solubility (1,200 mg/l).
Result	: EPIWIN BIOWIN (v4.00) predicts ready biodegradability using both nonlinear and linear methods
Reliability	: (2) valid with restrictions Data were obtained by modeling.
15.08.2003	

(6)

3.6 BOD5, COD OR BOD5/COD RATIO

3.7 BIOACCUMULATION

3. Environmental Fate and Pathways

Id 74-86-2
Date 21.10.2003

3.8 ADDITIONAL REMARKS

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type	: other: estimation
Species	: other
Exposure period	: 96 hour(s)
Unit	: mg/l
LC50	: = 496.148 calculated
Limit test	:
Analytical monitoring	: no
Method	: other: calculated
Year	: 2003
GLP	: no
Test substance	: as prescribed by 1.1 - 1.4
Remark	: Measured inputs to the program were melting point (-80.8 degrees C), boiling point (-84 degrees C), vapor pressure (5240 mm Hg) and water solubility (1,200 mg/l). This is a supporting study for the SIDS endpoint.
Reliability	: (2) valid with restrictions Data were calculated using a computer program.
05.09.2003	(7)
Type	: other: no data
Species	: Lepomis sp.
Exposure period	: 1 hour(s)
Unit	:
Method	: other
Year	:
GLP	: no data
Test substance	: as prescribed by 1.1 - 1.4
Remark	: Exposure of sunfish to 1000 ppm acetylene (at 18 degrees C) did not result in death. No other information was provided. This is a supporting study for the SIDS endpoint.
Source	: The primary source of the data was not cited in the OHM/TADS data file.
Reliability	: (4) not assignable There are not enough details to assign a reliability rating.
05.09.2003	(18)
Type	: other: no data
Species	: other: minnow
Exposure period	: 1 hour(s)
Unit	:
Method	: other
Year	:
GLP	: no data
Test substance	: as prescribed by 1.1 - 1.4
Remark	: Exposure of minnows (no species indicated) to 17 ppm acetylene in well-oxygenated water had no effect. This is a supporting study for the SIDS endpoint.
Source	: The primary source of the data was not cited in the OHM/TADS data file.
Reliability	: (4) not assignable There are not enough details to assign a reliability rating.
05.09.2003	(18)
Type	: other: no data
Species	: other: trout fingerlings
Exposure period	: 33 hour(s)

4. Ecotoxicity

Id 74-86-2

Date 21.10.2003

Unit	:	mg/l	
Method	:	other	
Year	:		
GLP	:	no data	
Test substance	:	as prescribed by 1.1 - 1.4	
Remark	:	Exposure of trout fingerlings to 200 ppm acetylene at 10-14 degrees C resulted in death to an unlisted number of fish. This is a supporting study for the SIDS endpoint.	
Source	:	The primary source of the data was not cited in the OHM/TADS data file.	
Reliability	:	(4) not assignable There are not enough details to assign a reliability rating.	(18)
05.09.2003			
Type	:	other: no data	
Species	:	Cyprinus auratus	
Exposure period	:		
Unit	:	mg/l	
Method	:	other	
Year	:		
GLP	:	no data	
Test substance	:	as prescribed by 1.1 - 1.4	
Remark	:	Exposure of goldfish to 400 ppm acetylene for 24 to 48 hours resulted in death to an unlisted number of fish. This is a supporting study for the SIDS endpoint.	
Source	:	The primary source of the data was not cited in the OHM/TADS data file.	
Reliability	:	(4) not assignable There are not enough details to assign a reliability rating.	(18)
05.09.2003			
Type	:	other	
Species	:	other: fingerling chinook salmon	
Exposure period	:	72 hour(s)	
Unit	:		
Method	:	other	
Year	:		
GLP	:	no data	
Test substance	:	as prescribed by 1.1 - 1.4	
Remark	:	The "critical level" at 72 hours for fingerling chinook salmon in brackish water was 3500 ppm. This is a supporting study for the SIDS endpoint.	
Source	:	The primary source of the data was not cited in the OHM/TADS data file.	
Reliability	:	(4) not assignable There are not enough details to assign a reliability rating.	(18)
05.09.2003			
Type	:	other: no data	
Species	:	other: young rainbow trout	
Exposure period	:	72 hour(s)	
Unit	:		
Method	:	other	
Year	:		
GLP	:	no data	
Test substance	:	as prescribed by 1.1 - 1.4	
Remark	:	The "critical level" at 72 hours for young rainbow trout in fresh water was 3000 - 5000 ppm. This is a supporting study for the SIDS endpoint.	
Source	:	The primary source of the data was not cited in the OHM/TADS data file.	
Reliability	:	(4) not assignable	

05.09.2003

There are not enough details to assign a reliability rating.

(18)

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type : other: calculated
Species : Daphnia magna (Crustacea)
Exposure period : 48 hour(s)
Unit : mg/l
EC50 : = 479.304 calculated
Analytical monitoring : no
Method : other: calculated
Year : 2003
GLP : no
Test substance : as prescribed by 1.1 - 1.4

Remark : Measured inputs to the program were melting point (-80.8 degrees C), boiling point (-84 degrees C), vapor pressure (5240 mm Hg) and water solubility (1,200 mg/l).

Reliability : (2) valid with restrictions
Data were calculated using a computer program.

Flag : Critical study for SIDS endpoint

15.08.2003

(7)

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

Species : other algae: green algae
Endpoint : growth rate
Exposure period : 96 hour(s)
Unit : mg/l
EC50 : = 274.86 calculated

Remark : Measured inputs to the program were melting point (-80.8 degrees C), boiling point (-84 degrees C), vapor pressure (5240 mm Hg) and water solubility (1,200 mg/l).

Reliability : (2) valid with restrictions
Data were estimated by a computer program.

Flag : Critical study for SIDS endpoint

15.08.2003

(7)

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA**4.5.1 CHRONIC TOXICITY TO FISH****4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES****4.6.1 TOXICITY TO SEDIMENT DWELLING ORGANISMS****4.6.2 TOXICITY TO TERRESTRIAL PLANTS**

4. Ecotoxicity

Id 74-86-2
Date 21.10.2003

4.6.3 TOXICITY TO SOIL DWELLING ORGANISMS

4.6.4 TOX. TO OTHER NON MAMM. TERR. SPECIES

4.7 BIOLOGICAL EFFECTS MONITORING

4.8 BIOTRANSFORMATION AND KINETICS

4.9 ADDITIONAL REMARKS

5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

5.1.1 ACUTE ORAL TOXICITY

5.1.2 ACUTE INHALATION TOXICITY

Type	: other
Value	:
Species	: human
Strain	:
Sex	:
Number of animals	:
Vehicle	:
Doses	: 100,000, 150,000, 200,000, 250,000, 300,000, 330,000 and 350,000 ppm
Exposure time	:
Method	: other
Year	: 1925
GLP	: no
Test substance	: as prescribed by 1.1 - 1.4
Remark	: It is evident from this study that the LD50 value in humans is greater than 10% (100,000 ppm).
Result	: Inhalation of 10% caused feelings of mild intoxication with paresthesia, and had a slight effect on reaction time. Fifteen percent caused distinct intoxication with talkativeness, sleepiness and inability to walk a straight line, but did not include symptoms of marked intoxication (even after an hour's inhalation). Marked intoxication was evident after inhalation of 20% for 4 minutes. Slight uncoordination of head movements was noticed after 20% had been inhaled for 18 minutes. Twenty five percent acetylene caused similar but more marked symptoms. An effect on writing, typewriting, simple reaction time or memory was not observed after inhalation of less than 20 - 25%. General uncoordination and aggressive behavior were noted after inhalation of 30% acetylene for 13 minutes. Inhalation of 33% or 35% caused unconsciousness within 7 and 5 minutes, respectively. Inhalation of 50% acetylene produced feelings of intense intoxication within 35 seconds and an unbearable feeling of suffocation in 70 seconds (after which the experiment was stopped).
Test condition	: Humans (number and sex were not listed) were administered acetylene (10 - 50 %) from a Douglas bag in the sitting position. No re-breathing was allowed. The acetylene was obtained from the Bon-Accord Acetylene Gas Company, and was prepared from calcium carbide and purified by passing through a lime-tower. Clinical signs were monitored and the concentration that produced unconsciousness (and exposure time) was listed. The effects of acetylene inhalation on memory, reflex times and muscular movement also were assessed.
Reliability	: (2) valid with restrictions The number of humans tested was not listed. Although the purity of the material was not listed, it is assumed that it is of fairly high purity since it was purified before use.
Flag	: Critical study for SIDS endpoint
05.09.2003	

(4)

Type	: Other
Value	:
Species	: Rat
Strain	:

5. Toxicity

Id 74-86-2
Date 21.10.2003

Sex :
Number of animals :
Vehicle :
Doses : 780,000 and 900,000 ppm
Exposure time :
Method : other
Year : 1925
GLP : no
Test substance : as prescribed by 1.1 - 1.4

Result : A concentration of 78% acetylene (780,000 ppm) produced anesthesia in 15 minutes. Acetylene did not cause marked excitement before anesthesia.

A concentration of 90% acetylene (900,000 ppm) caused respiratory failure in approximately 2 hours. It assumed that this concentration was lethal.

Test condition : Acetylene and other gases were tested for inhalation toxicity in a single strain of white rats of uniform weight (number and sex of animals and details about exposure were not provided).

Reliability : (4) not assignable
Not enough details are present to assign a reliability rating.

05.09.2003

(19)

Type : other
Value :
Species : dog
Strain :
Sex :
Number of animals :
Vehicle :
Doses :
Exposure time :
Method : other
Year : 1925
GLP : no
Test substance : as prescribed by 1.1 - 1.4

Remark : Inhalation of 50 dogs to 850,000 ppm increased respiratory volume and frequency and induced anesthesia, with rapid recovery. Therefore, the LD50 value in this study is greater than 850,000 ppm.

Reliability : (4) not assignable
There are not enough data to assign a reliability rating. The original reference was not consulted.

05.09.2003

(14)

5.1.3 ACUTE DERMAL TOXICITY

5.1.4 ACUTE TOXICITY, OTHER ROUTES

5.2.1 SKIN IRRITATION

5.2.2 EYE IRRITATION

5.3 SENSITIZATION

5.4 REPEATED DOSE TOXICITY

Type	:	
Species	:	
Sex	:	
Strain	:	
Route of admin.	:	
Exposure period	:	
Frequency of treatm.	:	
Post exposure period	:	
Doses	:	250,000, 500,000 and 800,000 ppm
Control group	:	
NOAEL	:	= 800000 ppm
Method	:	other
Year	:	1933
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	This is a supporting study for the SIDS endpoint. Since capillary hyperemia was not observed in rats exposed to higher concentrations of acetylene, it does not appear to be test-material related.
Result	:	The numbers of animals that died spontaneously are reported in the following table:

Animal	Conc. (%)	Daily Exposure Time (hours)	Number Of Days Exposed	Total Exposure Time (hours)	Deaths
Rat	25	1	7-93	7-93	6/16
Rat	50	2	1-8	2-16	9/10
Guinea Pig	50	2	1-9	2-18	7/7
Mouse	50	2	1-6	2-12	5/5
Rat	80	1/2	2-36	1-18	36/47
Rat	80	1	14	14	0/8
Guinea Pig	80	1	10	10	0/6
Rabbit	80	1	6-10	6-10	3/4
Dog	80	1	12	12	1/2

At the lower concentrations (concentrations were not stated) the animals appeared only slightly sleepy. At higher concentrations (70-80%), the majority of animals fell asleep after 15-20 minutes. In general, these animals were not in deep narcosis. The rats, rabbits, guinea pigs and dogs generally recovered from narcosis in a short time. However, the mice did not survive treatment. Some of the animals died spontaneously. Pneumonia was observed in most of these cases. Since pneumonia also was observed in control animals exposed only to air, it did not appear to be related to treatment. In treated animals that survived to termination, the authors found no evidence of cellular injury to the parenchymatous cells of the heart, lungs, liver, kidneys, or spleen. However, capillary hyperemia was observed in the liver, kidneys and spleen of some rats exposed to 250,000 ppm (the number was not stated). This effect was observed until at least the second day after the last exposure to the gas but was not evident in animals killed later (up to 5 days after the last exposure).

5. Toxicity

Id 74-86-2

Date 21.10.2003

Test condition

: Rats, mice, guinea pigs, rabbits, and dogs were exposed to acetylene in oxygen according to the scheme presented in the following table:

Animal	No. Tested/ Deaths/ Terminated	Conc. (%)	Daily Exposure Time (hours)	Number of Days Exposed	Total Exposure Time (hours)
Rat	16/6/12	25	1	7-93	7-93
Rat	10/9/1	50	2	1-8	2-16
Guinea Pig	7/7/0	50	2	1-9	2-18
Mouse	5/5/0	50	2	1-6	2-12
Rat	47/36/11	80	1/2	2-36	1-18
Rat	8/0/8	80	1	14	14
Guinea Pig	6/0/6	80	1	10	10
Rabbit	4/3/1	80	1	6-10	6-10
Dog	2/1/2	80	1	12	12

Thirty animals also served as controls. The number of controls for each species was not listed.

The animals were placed in glass cages that were air tight, and on one side the gassing apparatus was placed to introduce the gas, and on the other side of the cage an equal amount of air was exhausted out. This setup enabled the animals to move about freely without changes in air pressure and have the right amount of oxygen. The stream of acetylene/oxygen introduced amounted to 5 liters per minute, so that carbon dioxide buildup was ruled out for practical purposes.

As a rule, exposures were conducted daily. During the experiment, most of the animals (numbers were not stated) were weighed after various intervals. In some experiments, blood samples were taken at regular intervals from controls (numbers of animals were not stated).

Animals that survived to study termination were killed either right after the experiment or later by striking them on the head. A series of 30 controls also were killed by head strike. Three control animals showed signs of congestion from this method of killing. Most of the animals were killed and examined several hours after the last experiment. A portion were killed up to 5 or 14 days after the last exposure (individual numbers were not listed). Animals that died spontaneously the first 1-3 days after the last exposure also were examined. All animals were dissected and the organs (heart, lung, liver, kidney and spleen) were fixed in formalin or Zenker solution according to standard procedure, embedded in paraffin glycogenstain in celloiden and examined microscopically. In addition, frozen tissue slices were made and stained.

Conclusion

: The authors concluded that acetylene did not cause any sort of histologically detectable damage to parenchymatous cells at the concentrations tested.

Reliability

: (2) valid with restrictions
The study was not performed according to current standards.

11.09.2003

(11)

Type : Sub-chronic
Species : rat
Sex : male
Strain : other: albino
Route of admin. : inhalation
Exposure period : 6 hours per day
Frequency of treatm. : 5 days/week for 6 months
Post exposure period :
Doses : 28,700 ppm

5. Toxicity

Id 74-86-2

Date 21.10.2003

Control group : yes, concurrent no treatment
NOAEL : < 28700 ppm
Method : other
Year : 1957
GLP : no
Test substance : other TS

Remark : This is a supporting study for the SIDS endpoint.

Result : An acute study performed before this study showed that inhalation of 42,000 ppm for 6 hours did not cause lethality.
Chamber concentration: The concentration of material in the atmosphere of control animals was 2000 ppm. This was subtracted from the concentration analyzed in the atmosphere of exposed animals (30,700 ppm), to obtain a corrected exposure concentration of 28,700 ppm.

Signs of toxicity during exposure: On the first day of exposure, slight ataxia was noted within 7 minutes of exposure. After one half hour, most of the rats were lying on the chamber floor, in an early plane of anesthesia. A peculiar "pecking" motion of the head was exhibited throughout the first exposure. During remaining exposures, rats were observed to be in one position, lying either on the abdomen or on the side, with gross tremors of the head and extremities. The rats appeared to be unable to maintain balance. All animals recovered rapidly after exposures were terminated.

Signs of toxicity observed following exposure: Animals were depressed after exposure, and their fur was wet, discolored and ruffled. Rats were "unthrifty" after about 2 months on study. Eight (40%) of the rats died. Times of death were listed as 21, 34 (2 deaths), 46, 74, 95, 102 and 103 days. Two of the controls died. Over the course of the study, weight gain was slightly retarded in exposed rats.

Gross pathology of animals that died was limited to the lungs, which appeared dark red. The lungs remained distended when the thorax was opened, but no edema fluid was found. On palpation, the lungs had a firm consistency. A purulent empyema was observed in one rat.

In exposed rats that survived to termination, the lungs also were discolored and remained distended. Discoloration ranged from speckled red areas to a homogeneous, dark red, hemorrhagic appearance. Cut sections of lungs were a homogeneous, dark red color and either edema fluid or blood could be expressed from them. Lungs from 3 of the 12 surviving animals had cysts which contained a "cheesy material". The remaining organs appeared to be within normal limits. Microscopic pathology of the lungs showed definite pulmonary irritation.

Test condition : Animals: A group of 20 male albino rats (avg. weight 135 g) were exposed to an average concentration of 28,700 ppm methylacetylene for 6 hours/day, 5 days/week for 6 months. An equal number of rats was housed in the same laboratory to serve as controls. The laboratory temperature was 25 +/- 1 degrees C.

Exposure: Exposures were performed in 500 liter, stainless steel chambers with a water-sealed lid. The inlet was equipped with a suitable device to inject methylacetylene vapor, and the outlet was equipped with an orifice flowmeter, control valve and exhaust pump. Methylacetylene vapor was injected into the inlet at a fixed rate of flow from a large steel cylinder. A constant rate of flow was maintained during exposure with a reducing pressure valve and an orifice flowmeter, which was connected to a water manometer. The flow was constantly monitored. Methylacetylene was mixed with room air, which was drawn into the exposure chamber.

Test conduct: Animals were observed for signs of toxicity during and after

exposure (specific times were not listed). Animals were observed at least daily for mortality. Animals were weighed on days 0, 13, 24, 31, 38, 45, 60, 64, 71, 76, 85, 95, 102, 109, 120, 127, 137, 141, 146, 158, 165, 173, 179 and at termination (date was not stated). Gross pathologies of animals that died were performed as soon as possible after death. Gross pathologies of animals that survived the course of treatment were performed upon termination. Sections of lung, liver, kidney, heart, spleen and GI tract were examined microscopically.

Concentration of Test material: The concentration of material in the chamber was determined by drawing a known volume of the chamber atmosphere (measured with a wet-test meter) through 6 bubblers (in series) containing methanol. Samples were not drawn until the chamber concentration had equilibrated. The concentration of test material in each bubbler was determined separately. If an appreciable amount of material was found in the last bubbler, the samples were drawn at a slower rate. Blank samples from chambers containing control animals were run to determine the contribution of animal metabolites.

Solution from each bubbler was placed into a 250 ml volumetric flask, containing 50 ml of potassium mercuric iodide and 50 ml of 0.5 N sodium hydroxide. Methanol was added to make the contents up to 250 ml. The mixture was shaken and a 25 ml aliquot was titrated with 0.5 N sulfuric acid, using phenolphthalein as an indicator.

Test substance : The test material was methylacetylene (also known as propyne). Purity of the material is unknown.

Reliability : (2) valid with restrictions
Only one concentration was tested. The study is not as rigorous as a guideline study.

11.09.2003

(15)

Type : Sub-chronic
Species : Dog
Sex : male/female
Strain :
Route of admin. : Inhalation
Exposure period : 6 hours per day
Frequency of treatm. : 5 days/week for 6 months
Post exposure period :
Doses : 28,700 ppm
Control group : yes, concurrent no treatment
NOAEL : < 28700 ppm
Method : other
Year : 1957
GLP : No
Test substance : other TS

Remark : This is a supporting study for the SIDS endpoint
Result : Chamber concentration: The concentration of material in the atmosphere of control animals was 2000 ppm. This was subtracted from the concentration analyzed in the atmosphere of exposed animals (30,700 ppm), to obtain a corrected exposure concentration of 28,700 ppm.

Signs of toxicity during exposure: On the first day of exposure, marked salivation, excitability and muscular fasciculations were noted within 7 minutes of exposure. After 13 minutes, the dogs exhibited ataxia and mydriasis. After 30 minutes, one dog was lying on the chamber floor, in an early plane of anesthesia. One dog did not eat following the first exposure. Throughout the remaining exposures, similar signs of toxicity were observed. In addition, within 15 minutes of exposure, dogs appeared to be intoxicated (similar to alcohol). The dogs were excited and walked about the chamber, occasionally staggering and falling on the floor or against the

Test condition

sides. Shortly after termination of exposure, the dogs would lie quietly on the chamber floor.

Tonic convulsions occurred in at least one of the dogs on days 22, 110, 123 and 137. There was a prodromal syndrome consisting of 15-30 minutes of hyperexcitability, which terminated in a tonic convulsion of a few minutes' duration. Dogs recovered soon after the episodes.

Exposed dogs lost weight during the first 6 weeks of the experiment, attained their initial weight by week 14, and continued to gain weight until termination.

There was no effect of treatment on any hematological, urine or biochemical index of toxicity. The gross appearance of all organs (specific organs examined were not listed) and microscopic examinations of the lung, liver, kidney, heart, spleen and GI tract in exposed animals were normal.

: Animals: Two dogs (one male and one female) weighing 7.6 and 9.0 kg, respectively, were exposed to an average concentration of 28,700 ppm methylacetylene for 6 hours/day, 5 days/week for 6 months. Two male dogs were housed in the same laboratory to serve as controls. The laboratory temperature was 25 +/- 1 degrees C.

Exposure: Exposures were performed in 500 liter, stainless steel chambers with a water-sealed lid. The inlet was equipped with a suitable device to inject methylacetylene vapor, and the outlet was equipped with an orifice flowmeter, control valve and exhaust pump. Methylacetylene vapor was injected into the inlet at a fixed rate of flow from a large steel cylinder. A constant rate of flow was maintained during exposure with a reducing pressure valve and an orifice flowmeter which was connected to a water manometer. The flow was constantly monitored. Methylacetylene was mixed with room air, which was drawn into the exposure chamber.

Test conduct: Animals were observed for signs of toxicity during and after exposure (specific times were not listed). Animals were observed at least daily for mortality. Animals were weighed on days 0, 13, 24, 31, 38, 45, 60, 64, 71, 76, 85, 95, 102, 109, 120, 127, 137, 141, 146, 158, 165, 173, 179 and at termination (date was not stated).

Blood samples were taken for analysis of sedimentation rate, hematocrit, hemoglobin and white blood cell count at approximately 10-day intervals. Biochemistries consisting of icterus index, blood urea nitrogen, blood sugar, plasma chloride, and plasma carbon dioxide combining power and urinalyses (appearance, reaction, specific gravity, protein, sugar, occult blood and microscopic examination) were also performed at approximately 10-day intervals. Sulfobromophthalein sodium (BSP) tests were done at various intervals by administering a dose of 5.0 mg/kg to each dog and drawing blood samples 15 and 30 minutes later. The percent retention of BSP was determined by comparing the values to those of standards. Blood volumes were determined by injecting 1 ml of Evans blue dye and drawing blood 10 minutes later.

Gross pathologies of animals that died were performed as soon as possible after death. Gross pathologies of animals that survived the course of treatment were performed upon termination. Sections of lung, liver, kidney, heart, spleen and GI tract were examined microscopically.

Concentration of Test Material: The concentration of material in the chamber was determined by drawing a known volume of the chamber atmosphere (measured with a wet-test meter) through 6 bubblers (in series) containing methanol. Samples were not drawn until the chamber concentration had equilibrated. The concentration of test material in each

bubbler was determined separately. If an appreciable amount of material was found in the last bubbler, the samples were drawn at a slower rate. Blank samples from chambers containing control animals were run to determine the contribution of animal metabolites.

Solution from each bubbler was placed into a 250 ml volumetric flask, containing 50 ml of potassium mercuric iodide and 50 ml of 0.5 N sodium hydroxide. Methanol was added to make the contents up to 250 ml. The mixture was shaken and a 25 ml aliquot was titrated with 0.5 N sulfuric acid, using phenolphthalein as an indicator.

- Test substance** : The test material was methylacetylene (also known as propyne). Purity of the material is unknown.
- Reliability** : (2) valid with restrictions
- Only one concentration was tested in 2 dogs. The study is not as rigorous as a guideline study.

11.09.2003

(15)

5.5 GENETIC TOXICITY 'IN VITRO'

- Type** : Ames test
- System of testing** : Salmonella typhimurium TA97, TA98, TA100
- Test concentration** : up to 31 micrograms/plate
- Cytotoxic concentr.** :
- Metabolic activation** : with and without
- Result** : Negative
- Method** : Other
- Year** : 1984
- GLP** : no data
- Test substance** : as prescribed by 1.1 - 1.4

- Remark** : The test conditions used in the study were previously determined in a preliminary study that examined the 1) toxicity and mutagenicity of styrene oxide with log- and stationary-phase cells of TA100 with pre-incubation or plate incorporation, 2) mutagenicity testing of methylene chloride with the plate incorporation and preincubation techniques, 3) the effect of head-space volume and different types of shaking (during preincubation) on the mutagenic potential of styrene oxide and methylene chloride, 4) the effect of solvents and metabolic activation on the mutagenic potential of vapor-phase mutagens, and 5) the effect of preincubation time (10 - 60 min) on the mutagenic potential of styrene oxide. The results indicated that the optimal system used preincubation (10-30 minutes) with log-phase cells in full vials that were not shaken during preincubation.

- Result** : The concentrations used were lower than that recommended in guideline tests (5000 micrograms/plate) due to limited solubility in the solvent.
- : There was no effect of acetylene on the number of mutants in the absence of S-9. The average number of mutants in control strains TA97, TA98 and TA100 without S-9 were 142, 25.7 and 184.7, respectively. The average number of mutants in treated strains TA97, TA98 and TA100 without S-9 ranged from 97 - 106.3, 17.3 - 27.7 and 145.3 - 227.0, respectively.

There was no effect of acetylene on the number of mutants in the presence of rat S-9. The average numbers of mutants in control strains TA97, TA98 and TA100 with rat S-9 were 167.3, 34.3 and 174.0, respectively. The average number of mutants in treated strains TA97, TA98 and TA100 with rat S-9 ranged from 131.3- 144.7, 23.3 - 34.7 and 119.0 - 157.7, respectively.

There was no effect of acetylene on the number of mutants in the presence of hamster S-9. The average numbers of mutants in control strains TA97,

Test condition

TA98 and TA100 with hamster S-9 were 184.0, 38.3 and 199.7, respectively. The average number of mutants in treated strains TA97, TA98 and TA100 with hamster S-9 ranged from 121.7- 149.7, 23.3 - 36.0 and 144.7 - 167.7, respectively.

The test was valid, since both concentrations of each positive control induced at least a two-fold increase in the number of mutants with respect to solvent controls.

- : Salmonella typhimurium strains TA97, TA98 and TA100 were obtained from Dr. Bruce Ames, University of California, Berkeley. Stationary cells were grown overnight (16 hours) with shaking at 50 rpm; log-phase cells were grown on the day of the experiment by inoculating a fresh nutrient broth culture with fresh overnight culture (1:10 dilution) and shaking the culture for 4 hours at 50 rpm and 37 +/- 0.5 degrees C. Plates were incubated for 48 hours, and colonies were counted with a calibrated automatic cell counter.

Rat and hamster liver S9 were derived from male Sprague-Dawley rats and male Syrian Golden hamster, respectively. Both rats and hamsters were induced with 500 mg/kg Aroclor 1254 five days before liver harvest.

Positive controls were as follows: 50 and 100 micrograms/plate 9-aminoacridine for TA97 without S-9, 1 and 2 micrograms/plate 2-nitrofluorene for TA98 without S-9, 1 and 2 micrograms/plate sodium azide for TA100 without S-9, 1 and 2 micrograms/plate 2-aminoanthracene for all strains with rat S-9, and 0.5 and 1 micrograms/plate for all strains with hamster S-9.

Test vials contained (per plate): 500 microliters of medium or 5% S9 mix, 100 microliters of bacteria (cell number was not indicated), 100 microliters of acetylene (0.3, 1, 3, 10, or 31 micrograms/plate) in acetone solvent, acetone alone (negative control) or positive control, and 600 microliters of overlay agar. Test concentrations were chosen based on the results of a preliminary toxicity and solubility studies. Each vial contained the contents for 3 plates (without headspace). Vials were preincubated for 10 min at 37 degrees C in sealed one-dram glass vials in a temperature-controlled exposure chamber that completely surrounded the glass vial. The vial was not shaken during preincubation. Toxicity was determined by plating approximately 1,000 colonies on histidine-supplemented agar. A viability index was calculated by comparing the number of colonies present on a dosed plate to a solvent control plate. A viability index below 50% indicated excessive toxicity. A positive response was defined as at least a two-fold increase in the number of mutants in treated cells vs. solvent controls at two increasing dose levels.

Aliquots of each sample used in the Ames test were removed (times were not stated) and assayed for acetylene concentration by GC analysis [6' chromosorb 102 packed 1/4 " glass GC column (at 100 degrees C) with FI detection]. Each sample was assayed in triplicate, and mean concentration was calculated from the standard curve. Standards of test material were prepared by filling an evacuated 0.5 l gas bulb with acetylene and allowing the pressure to equilibrate to 1 atm. Samples were withdrawn through a septum in the bulb with a gas-tight syringe and chromatographed as described above. Duplicate injections were made for each point and a response curve of at least 3 points was established.

Test substance

- : Purity of the test material was not given; however it was mentioned that the material was obtained from Matheson Gas Company and was of the highest quality available.

Reliability

- : (2) valid with restrictions
Only three strains were used in the study.

Flag

- : Critical study for SIDS endpoint

16.10.2003

(16)

Type	: Bacterial reverse mutation assay
System of testing	: S. typhimurium TA98, TA100, TA1535 and TA1537 and E. coli WP2uvrA
Test concentration	: 0, 5, 10, 21 and 50%
Cytotoxic concentr.	: no data
Metabolic activation	: with and without
Result	:
Method	: other
Year	: 1994
GLP	: no data
Test substance	: other TS
Remark	<p>: Fifteen different gases were tested in the study. Some of the materials caused dose-dependent increases in revertants in the absence and presence of S9, and others did not. Results obtained in the study were similar to those reported by others, which validated the model.</p> <p>It is unknown why the results at 5 and 10 % in the absence of S9 were not considered to be positive, since the number of mutants appears to be at least twice that of the control. However, it is difficult to determine the exact number since the results were depicted graphically, with tic marks on the x axis (number of revertants) placed at 50.</p>
Result	<p>: Methyl acetylene did not cause an increase in mutations in any strain of Salmonella at any concentration in the absence or presence of S9 mix. Methylacetylene caused a dose dependent increase in the number of mutations in E. coli WP2 uvrA in the absence or presence of S9 mix. The authors stated that the effect was positive at concentrations $\geq 21\%$ without S9 mix (approximately ≥ 100 revertants/plate were detected) and $\geq 5\%$ with S9 mix (approximately ≥ 75 revertants/plate were detected). The number of revertants in the controls with and without S9 mix was < 25/plate.</p>
Test condition	<p>: Bacteria: S. typhimurium TA98, TA100, TA1535 and TA1537 were supplied by Dr. Bruce Ames, University of California, Berkeley and E. coli WP2 uvrA was supplied by Dr. M Ishizawa, Kyushu University, Fukuoka Japan. Stock cultures were stored at -80 degrees C. Bacteria were subcultured for 10 hours in nutrient broth before use.</p> <p>S9 and S9 mix: Liver homogenate (S9) was prepared from male Sprague Dawley rats (6 weeks old). Phenobarbital and 5,6-benzoflavone were used as inducers. The S9 mix contained 4 mM NADPH, 4 mM NADH, 5 mM glucose 6-phosphate, 8 mM MgCl₂, 33 mM KCl, 100 mM sodium phosphate buffer (pH 7.4) and 10-40% S9.</p> <p>Exposure system: Gas from the cylinder was collected into a 20-liter gas sampling bag. Another 20-liter gas sampling bag was filled with dilution gas (HEPA-filtered air). A fixed volume of the test gas was pumped out from the gas sampling bag and pumped into another gas sampling bag (gas dilution bag), which had been filled with a fixed amount of the dilution gas using a flowmeter and pump. The gas dilution bag was squeezed by hand to mix the gases. The concentrations used in the test were calculated using the volumes of test and dilution gases.</p> <p>Test material concentration: The concentration of gas in the bag was measured at the beginning of exposure using gas chromatography with FID/TCD detection. One ml of sample was withdrawn through the septum of the bag using a gas-tight syringe. Separations were performed using a Polapak Q column (3 mm x 2 m) or Silicone DC 550 column (3 mm x 2 m). Column temperature, injection temperature, and gas flow (N or He) were 70 degrees C, 120 degrees C and 50 ml/min, respectively. Concentrations used in the test were 0 (control), 5, 10, 21 and 50%.</p>

Mutation test: Bacterial plates were prepared using the spread method and the agar overlay method. For the spread method, 0.2 ml of a 0.5 mM histidine/biotin (for *S. typhimurium*) or 0.2 ml of a 0.5 mM L-tryptophan (for *E. coli*) solutions were poured into sterile tubes, to which 0.5 ml of a 0.1 M phosphate buffer or S9 mix was added. Test bacteria (.1 ml) were added and the entire solution was spread onto a minimal glucose agar plate. For the agar overlay method, 0.5 ml of a 0.1 M phosphate buffer or S9 mix were mixed with 0.1 ml of bacteria. Immediately after adding 1 or 2 ml of top agar containing 0.1 micromoles of L-histidine/D-biotin or L-tryptophan, the mixture was poured onto minimal glucose agar plates. Based on the results of a preliminary study with 1,3-butadiene (see below), it is assumed that the agar overlay method was used to test methyl acetylene.

Prepared plates were placed upside down (without lids) in a plate holder and the plate holder was placed in a 10-liter gas sampling bag through a hole cut with scissors. The hole was sealed by folding the opening 2 or 3 times and securing the fold with adhesive tape. The air in the bag was removed with a pump to check that the bag was air-tight. A flow meter and pump were connected to the gas dilution bag and approximately 1 liter of the test gas (at a known concentration) was pumped into the gas exposure bag. The gas in the exposure bag was then sucked out with a pump and the remaining air in the exposure bag was washed out. After washing out the air, the gas exposure bag was filled with the test gas at a fixed amount per plate. The plates were kept at 25 or 37 degrees C (exact temperature was not listed) for a "fixed period". It is assumed that exposure time was 14 hours based on the preliminary study with 1,3-butadiene (see below). After exposure was terminated, the gas in the exposure bag was removed, HEPA-filtered air was pumped into the exposure bag and the plates were removed. The plates were placed in a hood for 30 minutes to allow the test material to evaporate and lids were placed on them. The plates were then incubated inverted for 24 hours at 37 degrees C.

The conditions listed above were chosen based on the results of a preliminary study with 1,3 butadiene, in which the effect of the volume of gas per plate (357, 625, 1250, 2500 or 5000 ml/plate, which corresponded to 14, 8, 4, 2 or 1 plates/bag), the amount of S9 (50, 100, 200 or 400 microliters/plate), the exposure temperature (30 or 37 degrees C), exposure period (2, 4, 14, 24 or 48 hours), and amount of top agar (0, 1, or 2 ml/plate) were examined. For each experiment, one factor was changed at a time. 1,3 butadiene was not mutagenic if the exposure period was < 4 hours and was optimally mutagenic after 14 hours of exposure. The rate of mutagenicity was lower if bags contained 1-4 plates. A concentration of 100 microliters/plate S9 was optimal. Exposure temperature did not have a significant effect. The agar overlay method was more sensitive than the spread method. The conditions used for the gases optimized the chances for a positive result while conserving resources.

Test substance : The test material was propyne (CAS No. 74-99-7, methyl acetylene), used as supplied by Tokyo Kasei Co. Ltd.

Reliability : (2) valid with restrictions
Criteria for a positive or negative test were not given. Purity of the test material is unknown.

16.10.2003

(1)

5.6 GENETIC TOXICITY 'IN VIVO'**5.7 CARCINOGENICITY**

5. Toxicity

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5.8.1 TOXICITY TO FERTILITY

5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES

5.9 SPECIFIC INVESTIGATIONS

5.10 EXPOSURE EXPERIENCE

5.11 ADDITIONAL REMARKS

6.1 ANALYTICAL METHODS

6.2 DETECTION AND IDENTIFICATION

7. Eff. Against Target Org. and Intended Uses

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7.1 FUNCTION

7.2 EFFECTS ON ORGANISMS TO BE CONTROLLED

7.3 ORGANISMS TO BE PROTECTED

7.4 USER

7.5 RESISTANCE

8.1 METHODS HANDLING AND STORING

8.2 FIRE GUIDANCE

8.3 EMERGENCY MEASURES

8.4 POSSIB. OF RENDERING SUBST. HARMLESS

8.5 WASTE MANAGEMENT

8.6 SIDE-EFFECTS DETECTION

8.7 SUBSTANCE REGISTERED AS DANGEROUS FOR GROUND WATER

8.8 REACTIVITY TOWARDS CONTAINER MATERIAL

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10.1 END POINT SUMMARY

10.2 HAZARD SUMMARY

10.3 RISK ASSESSMENT